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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,578	04/27/2007	Noboru Yamazaki	Q92968	5136

23373 7590 04/14/2009

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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	**PAPER NUMBER**
1632	

MAIL DATE	DELIVERY MODE
04/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,578	YAMAZAKI ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15 and 27-31, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome.

Group II, claim(s) 16-22, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the pharmaceutical composition is hydrophilized by bonding a hydroxyl compound to the membrane of the liposome and/or the linker protein, wherein the hydrophilic compound has the formula (1).

Group III, claim(s) 16-21 and 23, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the pharmaceutical composition is hydrophilized by bonding a hydroxyl compound to the membrane of the liposome and/or the linker protein, wherein the hydrophilic compound has the formula (2).

Group IV, claim(s) 16-21 and 24, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the pharmaceutical composition is hydrophilized by bonding a hydroxyl compound to the membrane of the liposome and/or the linker protein, wherein the hydrophilic compound has the formula (3).

Group V, claim(s) 16-21, 25 and 26, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the pharmaceutical composition is hydrophilized by bonding a hydroxyl compound to the membrane of the liposome and/or the linker protein, wherein the hydrophilic compound is tris-aminomethane.

Group VI, claim(s) 16-21, 25 and 26, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the pharmaceutical composition is hydrophilized by bonding a hydroxyl compound to the membrane of the liposome and/or the linker protein, wherein the hydrophilic compound is tris-aminoethane.

Group VII, claim(s) 16-21, 25 and 26, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the pharmaceutical composition is hydrophilized by bonding a hydroxyl compound to the

membrane of the liposome and/or the linker protein, wherein the hydrophilic compound is tris-aminopropane.

Group VIII, claim(s) 1 and 32-41, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the sugar-modified liposome comprises a drug that is adrenocortical hormones.

Group IX, claim(s) 1 and 32-41, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the sugar-modified liposome comprises a drug that is antiinflammatroy drugs.

Group X, claim(s) 1 and 32-41, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the sugar-modified liposome comprises a drug that is immunosuppresive drugs.

Group XI, claim(s) 1 and 32-41, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the sugar-modified liposome comprises a drug that is anticancer drugs.

Group XII, claim(s) 1 and 32-41, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the sugar-modified liposome comprises a drug that is antimmicrobial drugs.

Group XIII, claim(s) 1 and 32-41, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the sugar-modified liposome comprises a drug that is antiviral drugs.

Group XIV, claim(s) 1 and 32-41, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the sugar-modified liposome comprises a drug that is angiogenesis inhibitors.

Group XV, claim(s) 1 and 32-41, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the sugar-modified liposome comprises a drug that is cytokines.

Group XVI, claim(s) 1 and 32-41, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the sugar-modified liposome comprises a drug that is chemokines.

Group XVII, claim(s) 1 and 32-41, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the sugar-modified liposome comprises a drug that is anti-cytokine antibodies.

Group XVIII, claim(s) 1 and 32-41, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the sugar-modified liposome comprises a drug that is anti-chemokine antibodies.

Group XIX, claim(s) 1 and 32-41, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the sugar-modified liposome comprises a drug that is anti-cytokine receptor antibodies.

Group XX, claim(s) 1 and 32-41, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the sugar-modified liposome comprises a drug that is anti-chemokine receptor antibodies.

Group XXI, claim(s) 1 and 32-41, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the sugar-modified liposome comprises a drug that is nucleic acid SiRNA.

Group XXII, claim(s) 1 and 32-41, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the sugar-modified liposome comprises a drug that is nucleic acid DNA.

Group XXIII, claim(s) 1 and 32-41, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the sugar-modified liposome comprises a drug that is neuroprotective factors.

Group XXIV, claim(s) 1 and 32-41, drawn to a pharmaceutical composition comprising a sugar-modified liposome having a sugar chain bound to the membrane of the liposome, wherein the sugar-modified liposome comprises a drug that is antibody drugs.

Group XXV, claim(s) 42-50, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound, wherein the hydrophilic compound has the formula (1).

Group XXVI, claim(s) 42-49 and 51, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound, wherein the hydrophilic compound has the formula (2).

Group XXVII, claim(s) 42-49 and 52, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound, wherein the hydrophilic compound has the formula (3).

Group XXVIII, claim(s) 42-49, 53 and 54, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound, wherein the hydrophilic compound is tris-aminomethane.

Group XXIX, claim(s) 42-49, 53 and 54, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound, wherein the hydrophilic compound is tris-aminoethane.

Group XXX, claim(s) 42-49, 53 and 54, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound, wherein the hydrophilic compound is tris-aminopropane.

Group XXXI, claim(s) 42 and 55-64, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound and the liposome comprises a drug that is adrenocortical hormones.

Group XXXII, claim(s) 42 and 55-64, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound and the liposome comprises a drug that is antiinflammatroy drugs.

Group XXXIII, claim(s) 42 and 55-64, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound and the liposome comprises a drug that is immunosuppresive drugs.

Group XXXIV, claim(s) 42 and 55-64, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound and the liposome comprises a drug that is anticancer drugs.

Group XXXV, claim(s) 42 and 55-64, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound and the liposome comprises a drug that is antimmicrobial drugs.

Group XXXVI, claim(s) 42 and 55-64, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound and the liposome comprises a drug that is antiviral drugs.

Group XXXVII, claim(s) 42 and 55-64, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound and the liposome comprises a drug that is angiogenesis inhibitors.

Group XXXVIII, claim(s) 42 and 55-64, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound and the liposome comprises a drug that is cytokines.

Group XXXIX, claim(s) 42 and 55-64, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound and the liposome comprises a drug that is chemokines.

Group XL, claim(s) 42 and 55-64, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound and the liposome comprises a drug that is anti-cytokine antibodies.

Group XLI, claim(s) 42 and 55-64, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound and the liposome comprises a drug that is anti-chemokine antibodies.

Group XLII, claim(s) 42 and 55-64, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound and the liposome comprises a drug that is anti-cytokine receptor antibodies.

Group XLIII, claim(s) 42 and 55-64, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound and the liposome comprises a drug that is anti-chemokine receptor antibodies.

Group XLIV, claim(s) 42 and 55-64, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound and the liposome comprises a drug that is nucleic acid SiRNA.

Group XLV, claim(s) 42 and 55-64, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound and the liposome comprises a drug that is nucleic acid DNA.

Group XLVI, claim(s) 42 and 55-64, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound and the liposome comprises a drug that is neuroprotective factors.

Group XLVII, claim(s) 42 and 55-64, drawn to a pharmaceutical composition comprising a liposome having a hydrophilized membrane surface to which no sugar chain is bound and the liposome comprises a drug that is antibody drugs.

2. The inventions listed as Groups I-XLVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The putative special technical feature common to groups I-XLVII is liposome with or without sugar chain modification and/or hydrophilized with hydroxyl group. Yamazaki et al., 2006 (US Patent No. 7,070,801 B2) discloses sugar-modified liposome having a sugar chain bonded to its membrane surface, preferably through a linker protein, and having excellent absorption qualities. The liposome is useful for therapeutic drug delivery to cancer cells (e.g. abstract). Yamazaki also discloses a liposome having a sugar chain bonded to the liposome membrane surface through a linker protein and both the liposome membrane surface and the linker protein are hydrophilized with a hydrophilic compound, such as tris(hydroxymethyl) aminomethane (e.g. column 3, lines 21-36). Preparation of liposome was well known in the art. Sekiguchi et al., 1995 (Colloids and Surfaces

B: Biointerfaces, Vol. 4, p. 287-296) discloses preparation of liposomes by using L-alpha-Dipalmitoyl phosphatidylcholine (DPPC), cholesterol, Dicetyl phosphate (DCP) and glycolipids (e.g. p. 288). There is no special technical feature that is contributed by the instant invention over the prior art. Thus, Groups I-XLVII do not relate to a single general inventive concept under PCT Rule 13.1.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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